K043304
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JAN 14 2005

510(k) Summary
Safety and Effectiveness
Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter

[per FD&C Act, Section 513 (I)(3)(A) and 21CFR Section 807.3]

Applicant:	Bioject Medical Technologies Inc. 211 Somerville Road Bedminster, New Jersey 07921
Contact Person:	Laurence A. Potter Director, Regulatory Affairs
Telephone:	908-470-2800
Fax:	908-470-1728
Email:	lpotter@bioject.com
Manufacturer: Establishment Registration No.	Bioject, Inc. 20245 S.W. 95th Avenue Tualatin, Oregon 97062 3023012
Sterilization Site: Establishment Registration No.	Dravon Medical 11465 SE Highway 212 Clackamas, Oregon 3021634

Device Trade Name:	Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter
Device Classification:	Class II, Special Controls
Common Name:	Vial Adapter
Regulatory Status: Product Code: C.F.R. Regulation No.: Description:	 LHI 880.5440 Intravascular Administration Set
Medical Specialty	General Hospital and Personal Use Devices

510(k) Summary Safety and Effectiveness
Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter (con't)

The device subject to this Notification is adding the fertility prescription drug Menopur® into it's Indication for Use, which is the only modification from the predicate device, Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter: ~~K041654~~ K041564.

Indications for Use:

The Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter is intended to allow needle-free withdrawal, reconstitution and transfer of Repronex® (menotropins for injection, USP) and/or Bravelle® (urofollitropin for injection, purified) and/or Menopur® (menotropins for injection, USP) and diluent from vials into an injection syringe for administration.

Predicate Device:

Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter: Bioject Medical Technologies, Inc., ~~K041654~~ K041564

Pharmaceutical Drug Relating To The Device's Intended Use:

The addition of the Menopur® indication is the only change from the previously cleared ~~K041654~~ Notification.
K041564

Ferring Pharmaceutical's prescription drug Menopur® (menotropins for injection, USP) was previously approved by FDA's Center for Drug Evaluation and Research (CDER) under NDA 21-663.

As in the original ~~K041654~~ Notification:
K041564

Ferring Pharmaceutical's prescription drug Repronex® (menotropins for injection, USP) was previously approved by FDA's Center for Drug Evaluation and Research (CDER) under NDA 21-047, and;

Ferring Pharmaceutical's prescription drug Bravelle® (urofollitropin for injection, purified) was previously approved by FDA's Center for Drug Evaluation and Research (CDER) under NDA 21-484.

* Ferring Pharmaceuticals Inc., Suffern, New York 10901, U.S.A.

Device Design and Performance:

The device which is the subject of this Notification is a sterile, injection molded and fully packaged component, which will be included into Ferring Pharmaceutical's Repronex®, Bravelle®, and Menopur® prescription drug kits to assist in needle-free reconstitution of these lyophilized drugs for injection.

The Vial Adapter component's physical design, description and performance are identical to that of the previously cleared predicate device, Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter: ~~K041654~~ K041564

Packaging and sterilization of the Vial Adapter are identical to that of the previously cleared predicate device, Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter: ~~K041654~~ K041564

In addition to the previously cleared Ferring fertility drugs in contact with the clear polycarbonate component (General Electric Lexan® 144R) and polycarbonate's non-cytotoxicity, this Notification provides testing which demonstrates that Menopur's®, biological activities are equivalent to a standard needle and syringe. The testing was performed to evaluate Menopur Assay results.

The data concludes that there are no substantial differences in the biological activity test results using a syringe with the Bioject vial adapter versus a syringe with needle.

The results, summarized in the following table, show that the assay numbers are virtually identical and within the experimental error range of the assay.

Menopur® Analyte	Syringe	Q-Cap
FSH	78.6 U/Vial	79.8 U/Vial
LH	77.1 U/Vial	77.4 U/Vial

No color additives are present in this component.

Ethylene oxide sterilization, ETO residual testing, and LAL Pyrogen testing support additional product safety. No other safety issues have been identified for the device component subject to this Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Mr. Laurence A. Potter
Director, Regulatory Affairs
Bioject Medical Technologies Incorporated
211 Somerville Road
Route 202 North
Bedminster, New Jersey 07921

Re: K043304
Trade/Device Name: Q Cap™ Needle Free Reconstitution 13mm Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: November 29, 2004
Received: December 2, 2004

Dear Mr. Potter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known):

Device Name: Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter

Indications for Use: The Q•Cap™ Needle-Free Reconstitution 13mm Vial Adapter is intended to allow needle-free withdrawal, reconstitution and transfer of Repronex® (menotropins for injection, USP) and/or Bravelle® (urofollitropin for injection, purified) and/or Menopur® (menotropins for injection, USP) and diluent from vials into an injection syringe for administration.

Laurence A. Potter
Director, Regulatory Affairs

Date November 29, 2004

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043394